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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/665,147	09/22/2003	Shin Sadano	2003_0988A	5797

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EXAMINER

DRODGE, JOSEPH W

ART UNIT	PAPER NUMBER
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1723

DATE MAILED: 03/08/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/665,147

Applicant(s)

SADANO ET AL.

Examiner

Joseph W. Drodge

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 February 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Madhavi et al patent 6,380,442 in view of Kanel et al patent 5,932,101. Madhavi et al disclose purification of marigold oleoresin (column 3, lines 5-11), optionally with a 1st step of solvent extraction with supercritical fluid (column 2, lines 38-42), and 2nd step of

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solvent extraction with an organic solvent (column 3, lines 14-16), 3rd step of cooling by freeze-drying together with precipitating (column 3, lines 54-61).

The claims differ in requiring the organic solvent to be of the ketone family.

Kanel et al teach solvent extraction of luteins and other carotenoids from plant material (column 5, lines 44-48 and Example 1a/column 9, lines 56 to column 10, line 4), by a multi-step solvent extraction process (especially column 7, line 64-column 8, line 7), in which supercritical fluids such as supercritical carbon dioxide [as in claim 4] and organic solvents and diluents such as the ketone solvent acetone [as in claim 5] are employed (see especially column 6, lines 12-19). It would have been obvious to one of ordinary skill in the art to have modified the processes of Madhavi et al, by substituting or supplementing the solvent extraction steps with a solvent extraction step employing an organic solvent such as acetone, as taught by Kanel et al, since the combination of supercritical fluids and the class of solvents including at least acetone are shown to enhance phase transfer and complete recovery of the desired solute(s) into the extraction solvent phase, and since acetone-type ketone and propanol solvents are interchangeably used in processes combining organic solvent extraction and supercritical solvent extraction, to obtain plant oil resin products such as carotenoids.

For claims 2 and 8-13, high lutein content of as much as 46 % are taught by Kanel et al at Table 1 and at least 50% by Madhavi et al at column 3, lines 62-65. Also, Madhavi et al disclose the solute/solvent mixture to have a quite low viscosity (see column 3, lines 14-16 "...free flowing solution" . Also, see column 3, lines 9-11

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concerning deriving of a product containing at least about 20% lutein esters, or higher depending upon total organic solvent employed and time of precipitation .

For claims 10-13, Madhavi at column 3, lines 14-16 disclose obtaining of a "free-flowing solution", hence solution of relatively low viscosity, at any rate the instantly claimed viscosities are inherent from recitation of a high content of total carotenoids and specifically lutein esters (column 3, lines 9-14 and 61-67).

For claim 3, additional carrier fluids and diluents are taught by Kanel at column 4, lines 3-7 and column 6, lines 12-23.

The pressures and temperatures of claims 6 and 7, for the supercritical carbon dioxide are taught by Kanel at column 4, lines 62-column 5, line 2.

Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Madhavi et al in view of Kanel et al as applied to claim 8 above, and further in view of Runge et al patent 6,261,598. Claim 14 differs in requiring the marigold resin to be in a soft capsule; such is taught by Runge at column 4, lines 21-26. It would have been additionally obvious to the skilled artisan to package the Madhavi/Kanel resin in a soft capsule, as taught by Runge, to make the resin easier to swallow or impart time release qualities when it is formulated into a foodstuff or medicine.

Applicant's arguments filed on February 6, 2006 have been fully considered but they are not persuasive. It is argued that Madhavi teaches obtaining a mixed carotenoid product containing lutein instead of lutein fatty acid component as a main ingredient. It is submitted that the instant claims merely recite obtaining a product or ingredient from marigold oleoresin and do not specify lutein-fatty acid ester.

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It is argued that Madhavi does not disclose use of ketone solvent. However, it is submitted that use of a similar solvent (isopropanol) is disclosed and that Kanel et al teaches that propanol type solvents are interchangeably used with other common solvents including acetone or, broadly ketone, in the extraction of organic products in processes also incorporating supercritical solvent extraction, such as extraction of carotenoid products (see the Examples of Kanel et al at columns 10-11).

It is argued that Kanel et al does not teach extraction with ketone preceding or following supercritical extraction. However, Kanel et al at column 6, lines 21-23 state that the feed may be dissolved in ketone or isopropanol co-solvent before being contacted with the supercritical solvent.

The paragraph bridging pages 1 and 2 of the Request for Reconsideration appears to be arguing that the primary Madhavi reference omits the limitation of cooling the solution prior to precipitating of product or ingredient. It is submitted that Madhavi clearly teaches cooling followed by precipitation at column 3, lines 45-49.

For claims 10-13, it is argued that Madhavi does not disclose product having at least 20 or 30% lutein-fatty acid ester, or the claimed relatively low viscosities. It is submitted that column 3, lines 10-11 explicitly disclose at least 20% such fatty acid ester. Also, Madhavi et al disclose the solute/solvent mixture to have a quite low viscosity (see column 3, lines 14-16 "...free flowing solution". Also, see column 3, lines 9-11 concerning deriving of a product containing at least about 20% lutein esters, or higher depending upon total organic solvent employed and time of precipitation.

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It is also submitted that Madhavi at column 3, lines 14-16 disclose obtaining of a "free-flowing solution", hence solution of relatively low viscosity, at any rate the instantly claimed viscosities are inherent from recitation of a high content of total carotenoids and specifically lutein esters (column 3, lines 9-14 and 61-67).

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Drodge at telephone number 571-272-1140. The examiner can normally be reached on Monday-Friday from 8:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Wanda Walker, can be reached at 571-272-1151. The fax phone number for the examining group where this application is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either private PAIR or Public PAIR, and through Private PAIR only for unpublished applications. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

JWD

March 6, 2006


JOSEPH DRODGE
PRIMARY EXAMINER